IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
COOKEVILLE DIVISION

ANDREW SCOTT RODRIGUEZ,	)	
	)	
Plaintiff,	)	**No. 2:08-cv-124**
	)	
v.	)	**Judge Aleta A. Trauger**
	)	**Magistrate Judge Bryant**
STRYKER CORPORATION, a Michigan corporation; and STRYKER SALES CORPORATION, a Michigan corporation,	)	
	)	
Defendants.	)	

DEFENDANTS STRYKER CORPORATION AND STRYKER SALES CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

No matter how his complaint is pled, whether in strict liability or negligence, plaintiff Andrew Rodriguez's claims against defendants Stryker Corporation and Stryker Sales Corporation (collectively "Stryker") are for a purported "failure to warn."[1] He contends Stryker failed to warn his surgeon of risks associated with the post-surgical continuous infusion of local anesthetics via pain pump into the intra-articular shoulder joint. To prevail, he must show that as of the date of his surgery in November 2004, Stryker knew, or had reason to know, that there was a risk of chondrolysis[2] associated with intra-articular placement of its pump, sufficient to

[1] Plaintiff has asserted causes of action for breach of implied warranty, but these fall with his failure to warn claims and, as to the "fitness for a particular purpose" claim in particular, for lack of reliance as well. *See* Section III.F, *infra*. While Plaintiff's complaint makes a half-hearted reference to a "design defect" [Complaint ¶ 32, Doc. No. 1], this theory has never been a serious part of the litigation. For example, no plaintiff, including plaintiff Rodriguez, has ever designated product design experts. Plaintiff cannot present evidence of "design defect" to the trier of fact without qualified design experts.

[2] "Chondrolysis" is generally understood to be a process, like arthritis, leading to cartilage damage. This condition has been described in the medical literature since the 1930's in other joints, long before the use of pain pumps or even local anesthetics. [*See, e.g.*, H. Waldenstrom, *On Necrosis of the Joint Cartilage by Epiphyseolysis Capitis Femoris*, 67 ACTA CHIR. SCANDINAV. 936-946 (1930); E. Compere, *Avascular Necrosis of Large Segmental*

prompt a duty to warn of that risk. *Harwell v. American Medical Systems, Inc.*, 803 F. Supp. 1287, 1299 (M.D. Tenn. 1992). Further, he must prove that the absence of a warning was a substantial cause of the use of the pain pump by his surgeon. *King v. Danek Medical, Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000).

By this motion for summary judgment, Stryker demonstrates that Plaintiff cannot raise a triable issue of material fact as to either essential element of his burden of proof. First, there is no evidence that, at the time of Plaintiff's surgery, Stryker or the medical community knew of even a potential association between continuous intra-articular infusion of local anesthetics and post-arthroscopic glenohumeral chondrolysis. [*See e.g.*, D. Petty et al, *Glenohumeral Chondrolysis After Should Arthroscopy: Case Reports and Review of Literature*, 32 AM. J. SPORTS MED. 509, 513 (2004) ("Petty Article"); Tucker Dec. Exh. C.] Lacking both actual and constructive knowledge of this purported risk, Stryker had no duty to warn as a matter of law.

Stryker's duty argument is hardly novel. For example, in *Phillippi v. Stryker Corp., et al,* 2010 WL 2650596 at *2-3 (E.D. Cal. July 1, 2010), the District Court granted summary judgment for Stryker, finding that as of July 2005 (eight months after plaintiff Rodriguez's surgery), Stryker had no duty to warn about a purported association between intra-articular pain pump use and chondrolysis. [Tucker Decl. Exh. D.] The absence of duty was also the basis for summary judgment in *Meharg v. I-Flow Corp.,* 2010 WL 711317 at *4 (S.D. Ind. March 1, 2010), which held that the local anesthetic manufacturer had no duty to warn as of February 2006. [Tucker Decl. Exh. E.]

Beyond the question of duty, Plaintiff's claims fail on the issue of causation. In order to prevail, Plaintiff must establish that Stryker's allegedly defective warning proximately caused his injury. Here, however, Plaintiff's surgeon, Dr. David Kuhn, relied on his training in prescribing Plaintiff's pain pump, rather than on any information from sales representatives or Stryker's Instructions for Use ("IFUs"). Thus, whatever the content of Stryker's labeling, Dr. Kuhn's

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Fracture Fragments of the Long Bones, 31-A J. BONE & JOINT SURG. 49-54 (1949); Declaration of Wendy Tucker in Support of Stryker's Motion for Summary Judgment ("Tucker Dec.") Exhs. A and B.]

treatment decisions were uninfluenced by it. Because Plaintiff cannot prove that Stryker's labeling influenced his prescribing physician and therefore caused Plaintiff's alleged injuries, Plaintiff cannot raise a triable issue on causation, and summary judgment for Stryker should be granted. *King v. Danek Medical, Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000).

A failure of proof as to both duty and causation precludes the factual predicate for Plaintiff's implied warranties and punitive damages claims as well, and requires that Stryker be granted summary judgment on all claims against it, or alternatively as to punitive damages alone.

II. FACTUAL BACKGROUND

A. Development And Regulation Of "Pain Pumps"

1. Description of the Pain Pump

All infusion pumps, including Stryker's, are generic medication delivery devices that are sold empty, with no pre-filled medications. The prescribing physician decides whether to prescribe an infusion pump, and what medications – alone or in combination – to use. The physician also decides the proper dosage, flow rate, and catheter placement. After the catheter is placed, the pump delivers set doses of the prescribed medication according to the doctor's regimen.

Infusion pumps deliver the same broad range of medications that could be administered by a syringe injection. As with a syringe, the choice of medication and dosage is based upon the doctor's professional judgment regarding his patient's needs. Thus, the "pain pump" is the modern-day equivalent of a syringe, performing by automation the same function as local injections administered by a health care professional.

2. History and Evolution of the Pain Pump

The pain pump was the logical outgrowth of the common syringe method of injection. As is often the case with new medical devices, the idea for a continuous infusion product came from the medical community, which requested that medical manufacturers produce a device to provide continuous flow, greater efficiency, and patient convenience.

Various forms of portable continuous infusion pumps have been used in medical practice

since at least the 1960s. [Arnold Henry Kadish et al., *A New Method for the Continuous Monitoring of Blood Glucose by Measurement of Dissolved Oxygen*, Clinical Chemistry, 11:9, 869-875 (1965); Tucker Decl. Exh. F.] One of the first medical articles on the subject aptly described the product as a "miniature syringe pump." [J.A. Parsons et al., *A Miniature Syringe Pump for Continuous Administration of Drugs and Hormones: The Mill Hill Infuser*, THE LANCET, (Jan. 8, 1977); Tucker Decl. Exh. G.] Infusion pumps used to control post-operative pain are in common usage today throughout the world. As a prescription device, manufacturers may sell the pump only to licensed health care providers and, by FDA regulations, only licensed physicians may prescribe one.

Stryker, a long-time manufacturer of medical devices, came to the pain pump market in 1999, when it began distributing McKinley Medical's "Outbound" infusion pump. In 2000, it acquired the product from McKinley. This product ultimately became the Stryker PainPump 1.0. While this was essentially a syringe and catheter operated mechanically, in 2002, Stryker introduced the PainPump 2.0, offering a programmable computer to regulate dosage and administer medication at intervals predetermined by the prescribing physician. Each model of pain pump is essentially a generic vessel for delivering medication in a place, manner, rate, amount, and type selected by the prescribing physician.

3. Federal Regulation of Pain Pumps

Medical devices are classified by the FDA into three classes. Class I devices involve the least regulation, as they are not used to sustain human life or prevent impairment of health, and pose no potential for unreasonable risk of injury. 21 U.S.C. § 360c(a)(2)-(3). Class II devices present a somewhat greater scope of use and potential risk, requiring higher standards for effectiveness and safety. *Id*. at §§ 360d, 360c(a)(1)(B). Stryker pain pumps are Class II devices. 21 C.F.R. § 880.5725 (b).

A new Class II medical device can be marketed only in compliance with the FDA premarket approval process, unless it is exempted by statute. 21 U.S.C. § 360e. The "substantial equivalency" exception permits a new device to be marketed without going through the

premarket approval process, if it is shown to be the substantial equivalent of a legally marketed device that existed before the Medical Device Amendments of 1976.

> Thus, if the FDA determines that the device has the same intended use and the same technological characteristics as the predicate device or determines that the device has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness, then the device will be deemed substantially equivalent.

[*In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1998 WL 964498 at *1 (E.D. Pa. Nov. 3, 1998); Tucker Decl. Exh. H.]

If the device is the substantial equivalent of the "predicate device," it may be marketed under a "510(k) notification" without further clinical study or premarket approval. 21 U.S.C. § 355(b)(1)(F). As infusion pumps had been in common use for years, Stryker's pumps were cleared under the 510(k) notification process and were found to be the substantial equivalent of earlier versions in existence prior to the Medical Device Amendments and to other pumps similarly approved. [Declaration of Jennifer Hoffman in Support of Stryker's Motion for Summary Judgment ("Hoffman Decl.") ¶ 3.]

The FDA must also approve all labeling. Package inserts (or "Instructions for Use") must provide detailed information regarding the known risks inherent with the product and the circumstances under which it is or is not appropriate to prescribe the device. *See* 21 CFR §355(b)(1)(F); 21 CFR §314.50(e)(2)(ii). At all times, Stryker's FDA-approved labeling included an indication for "intraoperative" use, as did the labeling for infusion pumps of multiple other manufacturers before Stryker entered the market. [Hoffman Decl. ¶ 4.] The term "intraoperative" simply means the site where the surgical procedure actually occurs. By approving this indication, FDA left to prescribing physicians, in their clinical judgment, the specific application for this prescription device in various surgical procedures and, in fact, the pumps are used in a wide variety of applications from OB/GYN to orthopedic surgery to breast augmentation.

B. Appearance And Investigation Of Post-Arthroscopic Glenohumeral Chondrolysis ("PAGCL")

1. 2004: At the time of Plaintiff's surgery, there was no scientific knowledge or reason to know that continuous infusion of local anesthetics into the shoulder could cause PAGCL.

Post-Arthroscopic Glenohumeral Chondrolysis (PAGCL) is a rare and recent phenomenon, the cause of which is neither known nor understood. The paper authored by Dr. Damon Petty in 2004, the year plaintiff Rodriguez had his shoulder surgery, was the first to describe the appearance of this condition. [Trippel Test. at 445:13-448:14, Tucker Decl. Exh. I (Dr. Stephen Trippel is a designated general causation expert for Plaintiff).] After reviewing the literature, Petty termed PAGCL a "rare" complication of routine shoulder arthroscopy, and acknowledged that "[l]ittle is known about the pathophysiology or natural history of this process. To our knowledge, glenohumeral chondrolysis has not been previously reported subsequent to shoulder arthroscopy." [Petty Article at 513, Tucker Decl. Exh. C.] Indeed, as Plaintiff's own designated Rule 26 general causation expert acknowledges, at the time of Plaintiff's surgery on November 15, 2004, there was no scientific knowledge or reason to know that continuous infusion of local anesthetics via pain pump into the glenohumeral joint could cause chondrolysis. [Trippel Test. at 445:13-21, Tucker Decl. Exh. I (no article as of June 2005 that attributed cartilage injury to local anesthetics administered by pain pump or any other method).]

2. 2005: The earliest reports to Stryker about potential cartilage damage implicated the use of epinephrine in the pump by some physicians, not the pump itself.

The first time in Stryker's awareness that potential damage to shoulder cartilage and pain pumps were even mentioned together, came in February of 2005, months after Plaintiff's surgery, when it received communications from Dr. Lonnie Paulos. Dr. Paulos expressed the sole concern that cartilage injury might potentially result with use of the drug epinephrine, which some physicians had been combining with local anesthetics in pain pumps. Specifically, he said that the mixture of epinephrine with local anesthetics created an "extremely acidic solution … . Without epinephrine it becomes less acidic and probably not an issue." Dr. Paulos never

suggested that either continuous infusion or the pain pump itself was responsible, nor that catheter placement was a factor, but instead focused on epinephrine.

Stryker investigated Dr. Paulos' concern, reviewing its own files and searching the FDA MAUDE database for any similar reports submitted by other manufacturers. [N. Petty Depo. at 68:16-69:21, 184:14-186:6; Tucker Decl. Exh. J.] Stryker also searched for literature concerning any relationship between use of Marcaine-epinephrine and necrosis. [*Id.*] Additionally, Stryker consulted a prominent anesthesiologist, who agreed that epinephrine was the likely cause. [Dr. Ilfeld Email, Tucker Decl. Exh. K.] Based on its investigation, Stryker found that although manufacturers had sold thousands of infusion pumps over many years, the phenomenon Dr. Paulos described had never been reported to Stryker, the FDA, or any other manufacturer, and had never even been mentioned in the medical-scientific literature. [N. Petty Depo. at 68:16-69:21, 184:14-186:6, Tucker Decl. Exh. J; Dr. Ilfeld Email, Tucker Decl. Exh. K.] Because Stryker's labeling already provided a caution regarding possible risks posed by epinephrine, stating that this drug may cause "necrosis," Stryker determined that no other action was indicated. [N. Petty Depo. at 68:16-69:21, 118:11-16, 207:4-7; Tucker Decl. Exh. J.]

3. 2010: To this day, there is no scientific consensus regarding the causes of PAGCL.

There is no data from any randomized clinical study establishing a statistically significant association between the administration of medication by infusion pumps and the development of chondrolysis, much less actual causation. Medical articles report that the etiology has yet to be identified with reference to the multitude of proposed and suggested factors in its development.[3]

On November 13, 2009, the FDA for the first time issued an advisory regarding continuously infused local anesthetics and the potential risk of chondrolysis, which it last updated on February 16, 2010. [Information for Healthcare Professionals, Tucker Decl. Exh.

[3] [*See* Daniel J. Solomon et al., *Glenohumeral Chondrolysis After Arthroscopy: A Systematic Review Of Potential Contributors And Causal Pathways,* 25 ARTHROSCOPY 1329-1342 (2009) ("Solomon Article") ("In summary, despite suggestions across existing case reports that certain factors appear correlated with PAGCL, without well-designed case-control studies that permit potential contributing factors or interest (i.e., exposures) to be examined in relation to PAGCL while adjusting for possible confounders, true risk factors for PAGCL cannot be identified [and] causal inference is not possible.") (emphasis added); Tucker Decl. Exh. L.]

M.] That advisory makes clear that, even as recently as February of this year, medical science still does not know what causes chondrolysis of the shoulder.

C. Plaintiff's Medical Course

1. Plaintiff received a Stryker pain pump at the conclusion of his shoulder surgery on November 15, 2004.

Plaintiff's shoulder was treated by Dr. John Kuhn at the Vanderbilt medical clinic. [Kuhn Depo. at 7:6-16, Tucker Decl. Exh. N.] By the time he went to see Dr. Kuhn for the first time on July 16, 2004, Plaintiff had a four-year history of shoulder instability. [*Id*. at 25:22-26:3, 27:5-16; Tucker Decl. Exh. N.] The impetus for his initial visit to Dr. Kuhn was a subluxation at work after he tripped and fell palm-down on his arm. [*Id*. at 27:5-23.] After an extended course of physical therapy, Plaintiff still had symptoms of pain and instability, so he agreed to surgery. [*Id*. at 28:6-31:6.] On November 15, 2004, Dr. Kuhn operated on Plaintiff's shoulder to repair a Hill-Sachs lesion and a labrum separation. [*Id*. at 31:25-34:13.] At the conclusion of the operation, Dr. Kuhn placed a pain pump catheter into Plaintiff's shoulder joint. [*Id*. at 41:15-21.]

2. Dr. Kuhn's prescription of a pain pump was uninfluenced by any Stryker representation or lack thereof.

Every aspect of Dr. Kuhn's decision to prescribe a pain pump to Plaintiff was driven by his training, experience, and course of practice, not any communication from Stryker. He first started using pain pumps during his tenure at the University of Michigan from 1994 to 2004. [*Id*. at 13:6-17.] He established his protocol for using pain pumps while at Michigan, and did not change it thereafter, even after his arrival at Vanderbilt in 2004. [*Id*. at 13:22-14:20.]

No information from Stryker played any role in Dr. Kuhn's decisions regarding pain pumps. Indeed, he was not even involved in the decision to use a Stryker pump, but simply used whatever pain pump the hospital happened to have in stock. [*Id*. at 16:21-17:5.] He has no recollection of any conversation with any Stryker employee or agent regarding pain pumps, and in any event affirmatively testified that his training in pain pumps did not rely on any sales representative. [*Id*. at 17:22-18:8.] He has no recollection of ever reviewing the Stryker Instructions for Use. [*Id*. at 55:11-13.] Moreover, his initial decision to use pain pumps and his

determination of their indications and contraindications was driven, not by any information from Stryker, but rather by the medical literature. [*Id*. at 62:5-63:6, 21:1-16.]

III. ARGUMENT

A. Summary Judgment Should Be Granted.

"The very mission of the summary judgment procedure is to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Harwell v. American Medical Systems, Inc.*, 803 F. Supp. 1287, 1291 (M.D. Tenn. 1992). There is no need for trial if "there is no genuine issue as to any material fact." Fed. R. Civ. Pro. 56(c) (2008).

> The moving party can prove the absence of a genuine issue of material fact by showing that there is a lack of evidence to support the nonmoving party's case. This may be accomplished by submitting affirmative evidence negating an essential element of the nonmoving party's claim, or by attacking the nonmoving party's evidence to show why it does not support a judgment for the nonmoving party.

Hughes v. Cook, 452 F. Supp. 2d 832, 835 (W.D. Tenn. 2006).

"So long as the movant has met its initial burden of demonstrating the absence of a genuine issue of material fact, the nonmoving party then must set forth the specific facts showing that there is a genuine issue for trial." *Emmons v. McLaughlin*, 874 F.2d 351, 353 (6th Cir. 1989). "The respondent must do more than simply show that there is some metaphysical doubt as to the material facts." *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1480 (6th Cir. 1989). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-248 (1986).

There is no genuine need for trial here. First, under Comment k to Section 402A of the Restatement (Second) of Torts, Stryker's only duty to Plaintiff was to warn of all known or reasonably knowable risks associated with its product, and any potential risk of chondrolysis associated with continuous infusion was unknown and unknowable at the time of Plaintiff's surgery in November 2004. Second, even if Comment k did not apply, Plaintiff would still be

obliged to prove that the pump was defective or unreasonably dangerous, which he cannot do because the pump conformed to the state of the art at the time of Plaintiff's surgery, and because Plaintiff failed to designate the requisite expert testimony. Third, Plaintiff cannot prove that any change to Stryker's warnings would have averted his alleged injuries because his surgeon did not rely on any information from Stryker in prescribing Plaintiff's pain pump. Because Plaintiff cannot prove a duty to warn or causation, his claims for strict liability, negligence, implied warranties, and punitive damages fail as a matter of law.

B. Plaintiff Cannot Prove That Stryker Had Any Duty To Warn Of A Potential Danger Of Chondrolysis Inherent In Its Device Prior To Plaintiff's Surgery.

1. Comment k forecloses each of Plaintiff's claims except failure to warn.

A pain pump is not a typical product. As a prescription medical device, it is an unavoidably unsafe product under Comment k to Section 402A of the Restatement (Second) of Torts. *Harwell v. American Medical Systems, Inc.*, 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992) (applying Comment K to a prescription medical device). Such products are neither defective nor unreasonably dangerous when they are "properly prepared and accompanied by proper directions and warning." *Id*. The Tennessee Supreme Court has applied Comment k in lieu of the TPLA in adjudicating product liability claims against the manufacturer of a prescription medical product. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428-29 (Tenn. 1994) (citations and punctuation omitted). Thus, Stryker's only duties to Plaintiff are to properly manufacture its product and properly warn about it. Plaintiff does not allege a manufacturing defect. Therefore, Comment k operates to foreclose each cause of action in Plaintiff's complaint, except the "failure to warn" claim.

2. Plaintiff cannot prove a duty to warn because Stryker neither knew nor had reason to know of any potential danger of chondrolysis associated with its pump as of November 2004.

Because Comment k limits Plaintiff to a single failure to warn claim, Stryker's "standard of liability under negligence and strict liability is essentially the same; namely, did the manufacturer provide an adequate warning?" [*Witherspoon v. Ciba-Geigy Corp.*, 1986 WL 2138

at * 2 (Tenn. Ct. App., Feb. 12, 1986); Tucker Decl. Exh. O.] "No manufacturer or seller can be required to, nor logistically do they have the ability to, imagine every unsafe scenario in which their product could be used by every consumer." *Shoemake v. Omniquip Int'l, Inc.*, 152 S.W.3d 567, 574 (Tenn. Ct. App. 2003). Neither are they "expected to warn of an unknown." *Smith v. Guadino*, 911 F. Supp. 296, 298 (E.D. Tenn. 1996).

Under Tennessee law, the learned intermediary doctrine requires only that a medical device manufacturer "reasonably disclose[] to the medical profession all risks inherent in the use of the drug which the manufacturer knew or should have known to exist." *Harwell*, 803 F. Supp. at 1299 (emphasis added); [*Nye v. Bayer Cropscience, Inc.*, 2009 WL 3295137 at * 12 (Tenn. Ct. App., Oct. 14, 2009) ("The learned intermediary doctrine is well established in Tennessee in relation to product liability claims against manufacturers and distributors of prescription drugs and medical devices."); Tucker Decl. Exh. P.] The manufacturer's constructive knowledge is "properly limited to the scientific and medical knowledge available" at the time. *Witherspoon*, 1986 WL 2138 at *3. Stryker's warning was therefore inadequate only if it failed to disclose a risk of which Stryker actually knew or that was known in the scientific and medical literature available as of November 2004. *Isbell v. Medtronic, Inc.*, 97 F. Supp. 2d 849, 862 (W.D. Tenn. 1998).

Under that knowledge standard, Plaintiff cannot prove that Stryker had a duty to warn. At the time of Plaintiff's index surgery in November 2004, Stryker had no actual knowledge of any risk of chondrolysis stemming from the use of its pain pump. [Hoffman Decl. ¶¶ 7, 8.] As to constructive knowledge, Plaintiff's own expert concedes there was not a single scientific article, even as of June 2005, that attributed any cartilage injury to any local anesthetic administered by any method. [Trippel Test. at 445:13-446:16, Tucker Decl. Exh. I;] *see Reid v. Sears, Roebuck and Co.*, 790 F.2d 453, 460 (6th Cir. 1986) (holding affidavit that contradicts prior sworn testimony cannot create an issue of fact sufficient to support an opposition to summary judgment). It is not hyperbole to say that, at the time of Plaintiff's index surgery in November 2004 and well after, there was literally no way for Stryker to know of any potential

risk of chondrolysis posed by its product. Indeed, even years later, medical science remains unable to attribute causation of chondrolysis to continuous infusion. [*See*, *e.g.*, Solomon et al., *supra* note 3 (concluding causal inference as of 2009 was impossible).] Stryker had no duty to warn of a danger of which it did not and could not have known. As a result, Stryker's motion for summary judgment should therefore be granted.

C. Even Were Comment K Held Not To Apply, Plaintiff Cannot Prove That Stryker's Pain Pump Was Defective Or Unreasonably Dangerous.

Even were Comment k held not to apply, Plaintiff would still have to prove, as a predicate to liability on any legal theory under the Tennessee Product Liability Act ("TPLA"), that the pain pump was "defective or unreasonably dangerous at the time it left defendant's control." *Tatum v. Cordis Corp.*, 758 F. Supp. 457, 460 (M.D. Tenn. 1991); Tenn. Code Ann. § 29-28-105(a). Plaintiff cannot meet this burden for two reasons. First, both the "defect" and "unreasonably dangerous" standards incorporate the state of scientific knowledge available to the manufacturer at the time and, as demonstrated above, the scientific literature as of the time of Plaintiff's surgery disclosed no potential risk of chondrolysis arising from Stryker's pump. Second, both standards require proof via specific expert testimony, which Plaintiff has failed to designate.

1. Plaintiff cannot prove Stryker's pump was defective or unreasonably dangerous because it conformed to the state of the art when it was put on the market.

"In determining whether a product is defective or unreasonably dangerous as to warrant liability, 'the state of scientific and technological knowledge available to the manufacturer or seller at the time the product was placed on the market, rather than at the time of injury, is applicable.'" *Brown v. Crown Equipment Corp.*, 181 S.W.3d 268, 281-82 (Tenn. 2005) (citing Tenn. Code. Ann. § 29-28-105(b)). If a defendant's product conforms to the state of the art when it was put on the market, it is neither defective nor unreasonably dangerous, and the defendant is not liable. *Murphy v. Owen-Illinois, Inc.*, 779 F.2d 340, 342-43 (6th Cir. 1985) (applying Tennessee law and affirming judgment for defendant on strict liability claim where

scientific evidence demonstrated plaintiff's level of exposure to defendant's product was considered medically safe at the time).

In *Abbott*, the plaintiff proceeded to trial on the theory of strict liability, and the jury was therefore required to determine whether the product at issue, a three-wheeled motorcycle, was defective or unreasonably dangerous. *Abbott v. American Honda Motor Co.*, 682 S.W.2d 206, 211 (Tenn. Ct. App. 1984). The jury was instructed, in pertinent part: (1) a "manufacturer is entitled to rely on the state of the art at the time the product is placed on the market rather than at the time of the injury"; (2) the "[s]cientific and technical knowledge available to the manufacturer" should be considered "in determining whether the product conformed to the state of the art at the time it was put on the market"; and (3) a finding that the product conformed to the state of the art necessitated a finding that it was neither defective or unreasonably dangerous. *Id*. On appeal, the court found "absolutely no merit in the Appellants' contention that the charge was inadequate in any way" and held that it "closely followed that of the statute and was in conformity with our case law." *Id*.

Here, it is undisputed that Stryker's warning conformed to the state of the art when it was put on the market because medical science knew of no risk of chondrolysis associated with pain pumps of which it could have warned. As has already been demonstrated, the scientific literature available to Stryker at the time of Plaintiff's surgery contained no indication that continuous infusion was even associated with chondrolysis. [Trippel Test. at 445:13-446:16, Tucker Decl. Exh. I;] *see Reid v. Sears, Roebuck and Co.*, 790 F.2d 453, 460 (6th Cir. 1986) (holding affidavit that contradicts prior sworn testimony cannot create an issue of fact sufficient to support an opposition to summary judgment). Stryker's pain pump was therefore not defective or unreasonably dangerous, because the state of the art did not allow Stryker to warn of a risk that was unknown to medical science. Because the pump conformed to the state of the art when it was put on the market, Plaintiff cannot meet his predicate burden of proof under the TPLA.

2. Plaintiff cannot prove Stryker's pump was defective or unreasonably dangerous because Plaintiff failed to designate the requisite expert testimony.

a. Plaintiff failed to designate the requisite expert testimony to prove that Stryker's pump was defective.

A defective product is proven by demonstrating that the product was in a condition "that renders it unsafe for normal or anticipatable handling and consumption." Tenn. Code. Ann. § 29-28-102(2). In a products liability action involving a technically complex medical device, expert testimony is required to establish that the product was defective. *Fulton v. Pfizer Hosp. Products Group, Inc.*, 872 S.W.2d 908, 912 (Tenn. Ct. App. 1993). "Under Tennessee law, to establish a defect in a product, the plaintiff must trace the injury to some specific error in construction or design of the product." *Harwell*, 803 F. Supp. at 1298. Generalized expert testimony finding fault with a product, unrelated to any specific defect in the particular device the plaintiff actually used, is "inadequate as a matter of law to demonstrate that there exist any genuine issues as to material facts." *King v. Danek Medical, Inc.*, 37 S.W.3d 429, 444 (Tenn. Ct. App. 2000).

None of Plaintiff's experts submitted reports regarding product defect, and none opine that there was any specific defect in the manufacture or design of the particular Stryker pump used by Plaintiff. [Tucker Decl. ¶ 18.] None claim to have seen or inspected that pump, or to know its particulars. [*Id.*] They do not even address the pump generally as it existed in November 2004, at the time of Plaintiff's index surgery. [*Id.*] Without expert testimony regarding any particular defect in the construction or design of the pump used by Plaintiff, Plaintiff's proof on the defect element is inadequate as a matter of law.

b. Plaintiff failed to designate the necessary expert testimony to prove that Stryker's pump was unreasonably dangerous.

In order to prove that a product is unreasonably dangerous, the plaintiff must utilize either the "consumer expectation" test or the "prudent manufacturer" test. The consumer expectation test requires proof that a product is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge

common to the community as to its characteristics." Tenn. Code. Ann. § 29-28-102(8). The prudent manufacturer test requires proof that "the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition. *Id*.

The consumer expectation test, which "requires the plaintiff to establish what an ordinary consumer purchasing the product would expect," has no application to a prescription medical device. *Brown v. Raymond Corp.*, 318 F. Supp. 2d 591, 595 (W.D. Tenn. 2004).

> Obviously, this test can only be applied to products about which an ordinary consumer would have knowledge. By definition, it could be applied only to those products in which everyday experience of the product's users permits a conclusion. For example, ordinary consumers would have a basis for expectations about the safety of a can opener or coffee pot, but, perhaps, not about the safety of a fuel-injection engine or an air bag.

Ray v. BIC Corp., 925 S.W.2d 527, 531 (Tenn. 1996) (emphasis in original). "Where ordinary consumers lack a basis for expectations about the safety of a product, the consumer expectation test will be inapplicable." *Brown*, 318 F. Supp. 2d at 596. An ordinary consumer cannot even purchase a pain pump (because it is a prescription medical device [Hoffman Decl. ¶ 3]), let alone have the everyday experience with it necessary to generate reasonable expectations. The consumer expectation test is therefore inapplicable here.

Without recourse to the consumer expectations test to prove unreasonable dangerousness, Plaintiff can only invoke the "prudent manufacturer" test, which requires proof about the reasonableness of the manufacturer or seller's decision to market a product assuming knowledge of its dangerous condition." *Ray*, 925 S.W.2d at 531 ("In contrast to the consumer expectation test, the prudent manufacturer test is more applicable to those circumstances in which an ordinary consumer would have no reasonable basis for expectations."). "Accordingly, expert testimony about the prudence of the decision [is] essential." *Id*. (emphasis added). Among the aspects that must be covered by such expert testimony is a risk-benefit analysis of a prudent manufacturer's decision to market a product, which must include the following factors:

> (1) The usefulness and desirability of the product – its utility to the user and to the public as a whole; (2) The safety aspects of the product – the likelihood that it will cause injury, and the probable seriousness of the injury; (3) The availability of a substitute product which would meet the same need and not be unsafe; (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility; (5) The user's ability to avoid danger by the exercise of care in the use of the product; (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Id. at 533, including n.10. Plaintiff has failed to designate any expert who will testify as to these required factors of the prudent manufacturer standard. [Tucker Decl. ¶ 18.] Thus, his proof on the unreasonable dangerousness element is also inadequate as a matter of law.

Because Plaintiff cannot prove that Stryker's pump was defective or unreasonably dangerous, he cannot satisfy his prerequisite burden of proof under the TPLA, and Stryker therefore cannot be liable for any of Plaintiff's alleged damages as a matter of law. Tenn. Code. Ann. § 29-28-105(a).

D. Even If Comment K Did Not Apply And Plaintiff Could Meet His Prerequisite Burdens Of Proof Under The TPLA, Plaintiff's Failure To Warn Claims Still Fail Because He Cannot Prove That Stryker's Warning Was Inadequate.

Even if Restatement § 402A Comment k did not apply, and even if Plaintiff could somehow present competent evidence demonstrating the required predicate that Stryker's pump was defective or unreasonably dangerous, Plaintiff still cannot prove the fundamental element of a failure to warn claim: inadequate warning. Again, a medical device manufacturer's warning is inadequate only if it fails to disclose a risk of which the manufacturer actually knew or should have known. *Isbell v. Medtronic, Inc.*, 97 F. Supp. 2d 849, 862 (W.D. Tenn. 1998). As set forth above at Section III.B.2, the evidence indicates Stryker neither knew nor should have known of any risk of chondrolysis associated with its pain pump as of the date of Plaintiff's surgery in November 2004, because such a risk was unknown to medical science. Plaintiff's failure to warn

claims, whether in strict liability or negligence, must therefore fail as a matter of law. *Barnes v. Kerr Corp.*, 418 F.3d 583, 590 (6th Cir. 2005) ("[T]he adequacy of a product warning can be decided as a matter of law where reasonable minds cannot differ as to its sufficiency.").

E. Plaintiff Cannot Prove That Any Failure To Warn On Stryker's Part Caused His Alleged Injuries.

Even if Plaintiff could prove that Stryker failed adequately to warn of chondrolysis, he "must [also] show that the failure to warn the physician was a cause in fact of [his] injury" in order to establish a valid cause of action. *Smith v. Pfizer, Inc.*, 688 F. Supp. 2d 735, 746 (M.D. Tenn. 2010). Causation requires proof that Plaintiff's surgeon's decisions surrounding his use of the pain pump "were influenced by any representation which the defendant[] made or failed to make." *King v. Danek Medical, Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000). Without such proof, Plaintiff's claim fails. *Id*.

Dr. Kuhn's decision to prescribe a pain pump for Plaintiff was uninfluenced by any Stryker representation or lack thereof. He developed his protocol for the use of pain pumps at the University of Michigan and never changed it thereafter. [Kuhn Depo. at 13:6-14:20, Tucker Decl. Exh. N.] His initial decision to use pain pumps and his determination of their indications and contraindications were driven, not by the content of any Stryker literature or lack thereof, but rather by the medical literature. [*Id*. at 62:5-63:6, 21:1-16.] He was not even involved in the decision to use a Stryker pump in Plaintiff's surgery, but simply used whatever pain pump the hospital happened to have in stock. [*Id*. at 16:21-17:5.]

Dr. Kuhn has no recollection of any conversation with any Stryker employee or agent regarding pain pumps, and in any event affirmatively testified that his training in pain pumps did not rely on any sales representative. [*Id*. at 17:22-18:8.] He also has no recollection of ever reviewing the Stryker Instructions for Use. [*Id*. at 55:11-13.] In short, there is no evidence that Dr. Kuhn was even aware of any Stryker representations when he prescribed Plaintiff's pain pump, let alone influenced by them. Plaintiff therefore cannot prove that any failure to warn by Stryker caused his alleged injuries.

F. Plaintiff Cannot Prove His Implied Warranty Claims.

Plaintiff has alleged claims for breach of implied warranty of merchantability and breach of implied warranty of fitness for a particular purpose. Each is precluded by the evidence, established above, that the pain pump conformed to the state of the art and was neither defective nor unreasonably dangerous. *Harwell*, 803 F. Supp. at 1302 (where medical device conformed to state of the art, plaintiff's claims for breach of implied warranties of merchantability and fitness for a particular purpose failed); [*see also Spence v. Danek Medical, Inc.*, 1998 WL 665760 at *6 (Tenn. Cir. Ct. June 17, 1998) (granting motion for summary judgment on breach of implied warranty claim where medical device was neither defective nor unreasonably dangerous); Tucker Decl. Exh. Q.] Moreover, a claim for breach of implied warranty of fitness for a particular purpose hinges on the prescribing doctor's reliance on the medical device manufacturer's skill or judgment to select or furnish the pain pump. Tenn. Code Ann. § 47-2-315; *Smith v. Pfizer, Inc.*, 688 F. Supp. 2d 735, 751 (M.D. Tenn. 2010). Here, Dr. Kuhn's sworn testimony is that he has no recollection of any communication with Stryker, and in any event had nothing to do with the selection of a Stryker pump over any other pump, but instead merely used whatever the facility happened to have on hand. [Kuhn Depo. at 17:22-18:8, 55:11-13, 16:21-17:5; Tucker Decl. Exh. N.] Dr. Kuhn's lack of reliance on Stryker in any regard forecloses Plaintiff's "fitness" claim for this reason as well.

G. The Undisputed Facts Demonstrate That There Is No Basis For Punitive Damages.

In Tennessee, a court may only award punitive damages "if it finds a defendant has acted either (1) intentionally, (2) fraudulently, (3) maliciously, or (4) recklessly." *Hodges v. S.C. Toof & Co.*, 833 S.W. 2d 896, 901 (Tenn. 1992). "A person acts intentionally when it is the person's conscious objective or desire to engage in the conduct or cause the result." *Id.* "A person acts fraudulently when (1) the person intentionally misrepresents an existing, material fact or produces a false impression, in order to mislead another or to obtain an undue advantage, and (2) another is injured because of reasonable reliance upon that representation." *Id.* "A person acts maliciously when the person is motivated by ill will, hatred, or personal spite." *Id.* "A person

acts recklessly when the person is aware of, but consciously disregards, a substantial and unjustifiable risk of such a nature that its disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances." *Id*.

"To prevail on a claim for punitive damages, the plaintiff must show that the defendant's negligence that proximately caused his or her injury reached a substantially higher level than ordinary negligence." *Duran v. Hyundai Motor America, Inc.*, 271 S.W.2d 178, 206 (Tenn. Ct. App. 2008). Indeed, "the Tennessee Supreme Court has reserved punitive damages for conduct that was so reprehensible that it must be both punished and deterred." *Id*. (emphasis added). "[B]ecause punitive damages are to be awarded only in the most egregious of cases, a plaintiff must prove the defendant's intentional, fraudulent, malicious, or reckless conduct by clear and convincing evidence." *Hodges*, 833 S.W. 2d at 901 (emphasis added).

Here, Plaintiff cannot even prove that Stryker was negligent, let alone adduce clear and convincing evidence that Stryker's conduct was so reprehensible and egregious as to warrant punitive damages. Indeed, the evidence is undisputed that Stryker did not know, and could not have known, of any risk of chondrolysis associated with its pain pump. [Hoffman Decl. ¶¶ 7, 8; Trippel Test. at 445:13-446:16, Tucker Decl. Exh. I.] Stryker therefore could have no "intent" to expose Plaintiff to a risk of chondrolysis because it did not know and could not have known of such a risk in the first place. Neither could Stryker have acted "fraudulently" because it logically could not intentionally misrepresent, or produce a false impression of, a risk of which it did not and could not know. There can be no "malice" where Stryker could not have known of a risk that Plaintiff's cartilage might be injured, let alone desired that result out of ill will. And Stryker could not have acted "recklessly" when it had no awareness of a risk, let alone conscious disregard for it.

Stryker's lack of any actual or constructive knowledge of a potential risk of chondrolysis associated with its pump in March 2004, particularly in light of the acknowledged uncertainty in 2009 that continuous infusion causes chondrolysis, means that, as a matter of law, Plaintiff

cannot meet the requirements for punitive damages. Moreover, a showing that a manufacturer complied with federal regulations, although not dispositive, is "certainly evidence that a manufacturer was not reckless." *Flax v. DaimlerChrysler Corp*., 272 S.W.3d 521, 536 (Tenn. 2007); *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 893 (2000) (good faith compliance with federal regulations weighs against a finding of punitive damages). Tennessee's product liability statutes "give refuge" to a manufacturer who operates in good faith and in "compliance of what the law requires him to do." *Tuggle v. The Raymond Corp*., 866 S.W.2d 621, 625 (Tenn. App. 1992). Plaintiff simply cannot produce a firm belief or conviction that Stryker acted with egregious intent, fraud, malice, or recklessness, particularly when the very anesthetics had been used during shoulder surgeries for years previously, as the 2009 FDA announcement stated.

In *Whitten*, the court dismissed the plaintiff's claim for punitive damages pursuant to motion for summary judgment because the plaintiff could not prove that the defendant manufacturer had any knowledge that its product posed a risk of the harm the plaintiff allegedly suffered. [*Whitten v. Michelin Americas Research & Dev. Corp*., 2008 WL 2943391 at *8 (W.D. Tenn. July 25, 2008) (applying Mississippi punitive damages law similar to Tennessee's); Tucker Decl. Exh. R.] The same result obtains here. Punitive damages are therefore inappropriate as a matter of law.

IV. CONCLUSION

For the foregoing reasons, Stryker's motion for summary judgment should be granted in its entirety.

DATED: November 1, 2010

SEDGWICK, DETERT, MORAN & ARNOLD, LLP

By: /s/ Wendy Tucker
Wendy Tucker, *admitted pro hac vice*
Attorneys for Defendants Stryker Corporation and Stryker Sales Corporation

CERTIFICATE OF SERVICE

I hereby certify that on November 1, 2010, a copy of the foregoing document was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Timothy A. Priest *[tapriest@pfph-law.com]*
Adam M. Priest *[ampriest@pfph-law.com]*
Pryor, Flynn, Priest & Harber
Suite 600, Two Centre Square
625 South Gay Street
Knoxville, Tennessee 37902
Attorneys for Plaintiff

Charles H. Thronson, Esq.
James T. Blanch, Esq.
John P. Ball, Esq.
Richard E. Mrazik, Esq.
PARSONS, BEHLE & LATIMER
One Utah Center, Suite 1800
201 S. Main Street
Salt Lake City, UT 84111
E-mail: RMrazik@parsonsbehle.com
Attorneys for Plaintiff

/s/ Betty J. Thomas
Betty J. Thomas